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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,709	09/18/2000	Hiroyuki Fujita	001200	4404
7590 08/05/2005			EXAMINER	
Armstrong Westerman Hattori McLeland & Naughton 1725 K Street NW Suite 1000 Washington, DC 20006			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/663,709

Applicant(s)

FUJITA, HIROYUKI

Examiner

Anish Gupta

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. The amendment submitted, 5-23-05, is acknowledged. Claims 1, 3, and 7 are pending in this application.

2. In the previous office action, it was unclear if the rejection over Yokoyama was withdrawn. This rejection was withdrawn in the previous office action based on the declaration the demonstrated the molecular weight content of polypeptides of at least 5000 is 21%.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yasumoto (JP06298794).

The claims are drawn to a angiotensin converting enzyme inhibitor.

Applicants have submitted a 1.132 declaration form Dr. Fujita which reproduces the working example in Yasumoto et al. According to the declaration, the polypeptide content of molecular weigh of at least 5,000 is more than 10% by weight and the has an inferior aftertaste as compared to the claimed composition.

Applicant's arguments and the declaration filed 5-23-05 have been fully considered but they are not persuasive.

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Applicants state that the declaration submitted is a reproduction of example 1 in the reference. However, this is not the case. On page 2 of the declaration, it is stated that the “homogenate was boiled at 100oC for 10 minutes, and then the resultant was allowed to stand. To the resultant was added 20mg thermolysin to carry out the hydrolysis reaction at 37oC and pH 7 for 3 hours.”

The reference, in example 1, states that the homogenate was left boiling for 10 minutes at 100oC. The supernatant was obtained and “[t]he operation conditions of thermolysin set reaction mixture to pH 7.0 by sodium hydroxide, and reaction temperature performed the standing reaction at 60oC for 5 hours. The amount of enzymes was added 1% of the weight of the amount of protein of a substrate” (see page 1 of examples). Note that the reaction conditions in the declaration are different than those disclosed in the examples in the way of reaction temperature and reaction time. Thus, the declaration is not commensurate in scope to the example recited in the reference. The MPEP states “[w]here the comparison is not identical with the reference disclosure, deviations therefrom should be explained.” Applicants have not provided any explanation as to the differences. The differences seem material and as such, the declaration is an ineffective showing to overcome the rejection.

Rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can normally be reached on (571) 272-0974. The fax phone number of this group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
ANISH GUPTA 8/4/09  
PRIMARY EXAMINER